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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

XLEAR, INC, a Utah corporation, Plaintiff, v. THE UNITED STATES FEDERAL TRADE COMMISSION, an agency of the United States of America, and ANDREW N. FERGUSON in his official capacity as Chairman of the Federal Trade Commission, Defendants.	**COMPLAINT** Case No. 2:25-cv-00484 Judge

Plaintiff Xlear, Inc., by and through its undersigned counsel of record, hereby complains of Defendant The United States Federal Trade Commission, and for its causes of action alleges as follows:

I. NATURE OF THE CASE

1. Pursuant to the Administrative Procedures Act, 5 U.S.C. § 702 (the "APA") and The Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, Plaintiff Xlear, Inc. ("Plaintiff") seeks declaratory relief confirming that: 1) Sections 5(a) (15 U.S.C. § 45(a)), and 12 (15 U.S.C. § 52) of the Federal Trade Commission Act (the "FTC Act") prohibit only marketing statements that are objectively "false" and/or constitute "unfair or deceptive acts"; 2) Sections 5(a) and 12 of the FTC Act do not require a party making a marketing statement to have substantiation for such statement and, thus, the Federal Trade Commission ("FTC") cannot use an alleged absence of substantiation as a substitute for, or equivalent of, a false statement or an unfair or deceptive act; 3) Sections 5(a) and 12 of the FTC Act do not require a party making a marketing statement to have substantiation for each such statement prior to making the statement; and, 4) in bringing an enforcement action (administrative or judicial) pursuant to the FTC Act, the FTC bears the burden to prove, by clear and convincing evidence, that any marketing statement is objectively false and/or constitutes "unfair or deceptive acts" and, thus, an alleged lack of substantiation, standing alone, does not state a cognizable claim for violation of the FTC Act. Alternatively, should the Court determine that the party making the statement referenced in section (2) above must have some sort of substantiation, Plaintiffs seek declaratory relief confirming that Sections 5(a) and 12 of the FTC Act do not require a party making a statement to have randomized controlled clinical trials (RCT) as proof that the statement is not false and/or constitutes "unfair or deceptive acts".

II. JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question jurisdiction) and 28 U.S.C. § 1346 (civil action against the United States), and 5 U.S.C. § 702 (the "APA").

3. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2) because this District is the venue in which "a substantial part of the events or omissions giving rise to the claim occurred . . . ."

4. This Court may grant the relief requested pursuant to 28 U.S.C. § 2201 (authorizing declaratory relief); and, 5 U.S.C. §§ 701-706 (providing for judicial review of agency action under the APA, and identifying vacatur and remand of agency action as the default remedy).

III. PARTIES

5. Plaintiff is a Utah corporation with its principal place of business at 723 South Auto Mall Drive, American Fork, UT 84003. Plaintiff was founded in June 2000. Plaintiff develops and manufactures a suite of xylitol-based hygiene products (e.g., nasal sprays, toothpastes, mouthwashes, chewing gums) that help promote hygiene and health and reduce the incidences of disease. Plaintiff's products are non-pharmaceutical. Plaintiff conducts business across the United States and around the world. Plaintiff's products are sold at leading retailers (e.g., Walmart, Target), pharmacies (e.g., CVS, Rite-Aid, Walgreens), markets (e.g., Whole Foods), health food stores, and online (e.g., Amazon.com).

6. In order to market its products, Plaintiff makes statements about hygiene and its products across a broad range of media, including: appearances, speeches, press releases, digital

advertising, social media, print advertising, radio advertising, in store advertising, online advertising, events, media outreach, product packaging, and sponsorships.

7. In order to educate the consumer, Plaintiff also makes statements about the benefits of hygiene generally, as well as the benefits of Plaintiff's products specifically. For example, Plaintiff's nasal spray's product packaging has always carried a research-based graphic showing how the nasal spray blocks bacterial adhesion. During the COVID-19 outbreak, Plaintiff became aware of a body of evidence showing how Xlear nasal spray similarly blocked the adhesion of SARS-CoV-2, the virus that causes COVID-19, with the effect of lessening the effects of the virus. (As discussed below, during the pandemic the FTC sued Mr. Jones and Plaintiff alleging that Plaintiff's educational efforts violated the FTC Act.)

8. Other published research has found that saline-based nasal sprays, including Xlear, are effective at reducing the risks of respiratory infections, including COVID, and reducing the duration and severity of upper respiratory infections when used by those already infected. *See*, *e.g.*, Little, Paul et al., Nasal sprays and behavioural interventions compared with usual care for acute respiratory illness in primary care: a randomised, controlled, open-label, parallel-group trial, The Lancet Respiratory Medicine, Volume 12, Issue 8, 619 – 632, available at https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(24)00140-1/fulltext (the "Lancet Study").

9. Under the brand name Spry, Plaintiff also develops, makes, markets and sells a suite of dental hygiene products (such as toothpaste, chewing gum and mouthwash) that contain xylitol. Decades of scientific research has determined that xylitol denies the bacteria that causes tooth decay its food source and inhibits its adhesion and acid production, with the overall result being diminished incidence of tooth decay. Due to concerns about the safety of significant and

long-term exposure to fluoride, particularly in children, there are efforts underway to reduce the use of fluoride. For example, both Florida and Utah recently banned the use of fluoride in drinking water. As a result, an effective, alternative approach to dental hygiene is of particular importance to public health at this time. Xylitol-based dental hygiene products (such as Spry products) are a science-based alternative to the current fluoride-based approach. From both a commercial and public interest perspective, Plaintiff should now be vigorously educating people about the use of xylitol-based dental hygiene generally, and Plaintiff's products specifically.

10. Such statements, specifically those set out in paragraphs 7 through 9 above, are evidence- and science-based and are truthful and not misleading.

11. However, Plaintiff is not now making these and other research-backed statements to the public about the benefits of hygiene generally, and Plaintiff's products specifically, out of fear of yet another FTC enforcement action against the Plaintiff alleging lack of substantiation under the FTC Act.

12. Plaintiff's inability to make such statements is causing real and concrete harm to Plaintiff, and the public, because, among other things: 1) it reduces the ability of Plaintiff to educate consumers about the value of hygiene generally, and Plaintiff's products specifically, in promoting health and reducing risk of disease, which harms consumers by putting their health at risk and reducing their health freedom; 2) it reduces the ability of Plaintiff to sell its products, thereby diminishing the company's profits and overall value; and, 3) it limits Plaintiff's First Amendment right to free speech.

13. Defendant FTC is the agency of the Federal Government charged with implementing the FTC Act. The FTC devised and has enforced the extra-statutory requirement for substantiation under FTC Act sections 5(a) and 12. 15 U.S.C. §§ 45(a), 52. The FTC has

previously sued Plaintiff alleging violations of these Sections of the FTC Act, and specifically alleging that Plaintiff violated the FTC Act by making unsubstantiated claims. The FTC has also made clear, through industry guidance published in 2022, that, in the context of health-related claims (like those that Plaintiff has made and would be making but for the acts of the FTC challenged herein), it imposes a "rigorous substantiation standard of competent and reliable scientific evidence," and that it will bring enforcement actions against marketers who, in the FTC's opinion, are making claims without first satisfying that "rigorous" requirement. FTC, Health Products Compliance Guidance (published December 2022) at 11. But it is indisputable that the plain language of the FTC Act does not make, and has never made, any kind of marketing claim actionable merely because it is, in the FTC's opinion, "unsubstantiated."

14. Defendant Andrew N. Ferguson is the Chairman of the FTC, and he is named in this action in his official capacity.

IV. FACTUAL AND PROCEDURAL BACKGROUND

15. Early in the COVID-19 pandemic, Plaintiff became aware of a body of evidence demonstrating that saline nasal sprays generally provided an additional layer of defense against COVID-19. For example, a number of scientific studies using simple saline-alone nasal sprays determined that early treatment for those already infected with the virus reduced the duration and severity of the illness and reduced the rate of hospitalizations. Additionally, a series of *in vitro* studies determined that Xlear, and/or the ingredients in Xlear, were virucidal, anti-viral, and blocked adhesion of the COVID-19 virus.

16. Having studied the data on the efficacy of nasal sprays as a countermeasure to COVID, and Xlear specifically, Plaintiff made certain statements to inform Americans about the use of nasal sprays as an additional layer of protection against COVID-19.

17. On July 29, 2020, the FTC sent Plaintiff a warning letter alleging that Plaintiff's statements about COVID-19 lacked substantiation and, therefore, violated the FTC Act (and the COVID Consumer Protection Act, which piggybacks on the FTC Act). Plaintiff attempted to work with the Government to address the FTC's concerns. However, ultimately, the FTC's demands in these negotiations were untenable and, in Plaintiff's determination, unlawful.

18. On October 28, 2021, the Department of Justice, acting on behalf of its client, the FTC, filed a lawsuit against Plaintiff and its CEO, Mr. Nathan Jones, alleging violations of the FTC Act. *United States v. Xlear*, No. 2:21-cv-00640-RJS-DBP (D. UT filed Oct. 28, 2021). Specifically, the FTC alleged, *inter alia*, that Plaintiff (and Mr. Jones) violated the FTC Act by making statements about Xlear Nasal Spray without possessing RCTs that prove, or substantiate, these claims. It was the FTC's position that a party making such statements bears the burden of proving that the statements are supported by one or more RCTs—independent of whether the statement is objectively true and/or not misleading. Which is to say, under the FTC's substantiation scheme, a party is guilty of violating the FTC Act if it does not have RCT evidence, even if its statement is objectively true and not misleading.

19. On March 10, 2025—after four years of vexatious litigation costing Plaintiff and Mr. Jones upwards of $3 million—the Government, *sua sponte*, requested the Court dismiss the case, with prejudice (via a stipulation joined by Plaintiff and Mr. Jones). *United States v. Xlear*, No. 2:21-cv-00640-RJS-DBP (D.C.UT dismissed Mar. 10, 2021).

20. As set out in detail below, Plaintiff now seeks declaratory relief that Sections 5(a) and 12 of the FTC Act, as written, do not and cannot impose an affirmative burden of substantiation on regulated parties. The consequences of such a declaration to Plaintiff are significant and will directly redress the clear and otherwise irreparable harm that Plaintiff is

suffering as a result of the FTC's ongoing assertion that an alleged lack of substantiation, standing alone, gives rise to liability under the FTC Act. Among other things, such a declaration will make clear to the FTC that it has the affirmative burden of proving that a challenged claim is false or misleading, and cannot proceed merely on an alleged absence of substantiation. In other words, the FTC cannot shift the burden of proof to the marketer to prove its claims are substantiated merely by alleging an absence of substantiation—something it has done in the past, including with Plaintiff. In the alternative, if the Court determines that Sections 5(a) and 12 somehow impose a substantiation burden (despite the fact that, as explained below, the word "substantiation" does not appear in the Act itself), Plaintiffs seek declaratory relief that Sections 5(a) and 12 do not require RCT studies as substantiation. The FTC has required RCT substantiation for health-related claims in the past, including with Plaintiff, and has clearly expressed its expectation that marketers will possess RCT substantiation before making product claims.

V. LEGAL BASIS

A. Declaratory Relief is Appropriate Here

21. The Federal Declaratory Judgment Act, codified at 28 U.S.C. § 2201, in conjunction with FRCP 57, allows parties to seek a judicial declaration of their rights, duties, or obligations in a case of actual controversy, providing a way to resolve outstanding legal uncertainties. In this case, simply, to issue a declaration that Sections 5(a) and 12 do not prohibit statements about a product solely because those statements are allegedly unsubstantiated.

22. Pursuant to the APA, and specifically 5 U.S.C. § 702, sovereign immunity has been waived in an action, like this one, brought by "[a] person suffering legal wrong because of

agency action, or adversely affected or aggrieved by agency action with the meaning of a relevant statute," and Plaintiffs here are "entitled to judicial review thereof."

23. The FTC statutory scheme does not preclude judicial review of the actions challenged herein. Nor is the action at issue here committed to the FTC's discretion.

24. The agency action that Plaintiff challenges in this proceeding is final and there is no other adequate remedy available in court. More specifically, the agency action at issue here "marks the consummation of the agency's decision making process, and [ ] either determine[s] rights or obligations or occasion[s] legal consequences." *Alaska Dep't of Envtl. Conservation v. EPA*, 540 U.S. 461, 482, 137 L.Ed.2d 967, 124 S.Ct. 873 (2004) (cleaned up). The FTC has made it clear, both in its official published guidance and by filing suit against Plaintiff and others, that there are serious "legal consequences" that flow from a marketer making claims about a product without possessing what the FTC deems to be adequate substantiation.

25. Moreover, the harm caused to Plaintiff by the FTC's actions is direct and immediate because, among other things, Plaintiff is self-censoring its speech, including its product advertising, out of the legitimate concern of FTC enforcement action.

26. Furthermore: (1) delayed review would cause hardship to the Plaintiff, who will continue to self-censor and deprive the "marketplace of ideas" of important, health-related information so long as this dispute is unresolved, (2) judicial intervention would not inappropriately interfere with further administrative action, but would in fact provide much-needed clarity on a critical and purely legal question, and (3) given the purely legal nature of this dispute, the courts would not benefit from further factual development of the issues presented.

27. This action is further proper because there are no adequate alternative remedies available for Plaintiff to obtain the relief they are seeking herein. Alternatively, any

administrative remedies would be futile because the FTC's position on the substantiation standard challenged herein is well-established and will not change absent judicial intervention, and any remedy that might be provided through administrative proceedings is inadequate. Additionally, the issues presented here involve serious constitutional questions requiring immediate judicial intervention.

28. Notwithstanding the FTC's dismissal of the prior lawsuit, the FTC's substantiation scheme continues to unlawfully harm the Plaintiff. Most importantly, while the dismissal protects the Plaintiff from additional lawsuits for any claims brought in the prior case and claims that could have been brought in that case, it offers no protection from the FTC filing a lawsuit for any statements the Plaintiff (or any others) might make in the future. Additionally, the dismissal provides Plaintiff (nor any other party) no guidance as to what the FTC can versus cannot, or will versus will not, require for compliance with the FTC Act. Moreover, any administrative action the present administration might or might not take cannot bind future administrations. The chilling effect of this uncertainty on the Plaintiff is concrete and will be redressed by the declaration Plaintiff seeks.

29. Courts have held that "a plaintiff can demonstrate a cognizable injury [as a predicate to declaratory relief] in a pre-enforcement challenge only if it establishes that (1) it has "an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute," and (2) "there exists a credible threat of prosecution thereunder." *See Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) (*quoting Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289 (1979)).

30. Plaintiff meets these requirements. Having already been sued by the FTC for making allegedly unsubstantiated statements, the threat of future enforcement actions is beyond

credible. *See Braidwood Mgmt. v. Equal Emp't Opportunity Comm'n*, 70 F.4th 914 , 923 (5th Cir. 2023)(credible fear of an enforcement action satisfies requirements for ripeness and justiciability). Moreover, during the pendency of the prior lawsuit (in December 2022), the FTC published official guidance making clear its expectation that marketers of health-related products will meet its "rigorous substantiation standard," which generally requires "randomized, controlled human clinical testing"—something that did not even exist when the FTC Act was enacted—and that the absence of such substantiation should be understood to create an omnipresent threat of legal action.

31. As a result of this threat and uncertainty, Plaintiff has no alternative but to continue refraining from making truthful, non-misleading, and scientifically-based factual statements concerning the benefits of hygiene products, including Plaintiff's products, against various pathogens. *See Elrod v. Burns*, 427 U.S. 347, 373, (1976) (plurality opinion)("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury."); *see also Braidwood Mgmt. v. Equal Emp't Opportunity Comm'n*, 70 F.4th 914 , 926-27 (5th Cir. 2023)(chilling effect on Constitutional rights from potential enforcement satisfies basis for seeking declaratory relief). This forced suppression of protected speech comes as America faces a series of serious respiratory outbreaks—including bird flu, influenza, COVID, and RSV. Knowledge that using a non-invasive, simple, inexpensive, safe and readily-available nasal spray can reduce risks from these diseases is important information that Americans should be aware of, especially given the serious respiratory diseases the nation now faces. As a corollary, if more Americans knew that Xlear and other nasal sprays could protect them from upper respiratory illness, it follows that demand for and sales of Xlear nasal spray would increase. If Plaintiff did not face the likelihood of future FTC enforcement, Plaintiff

would have taken, and would be taking, steps to raise public awareness of this science, such as posting on social media and generally advertising.

32. However, based on its prior actions against Plaintiff and its published guidance, the FTC would almost certainly conclude that any such statements run afoul of the FTC's interpretation of the FTC Act as requiring substantiation, in particular RCT substantiation. For example, the Lancet Study did not test Xlear *per se*. Throughout the prior lawsuit, the FTC refused to consider data from tests done on functionally equivalent products as substantiation for Plaintiff's statements. Additionally, the Lancet Study looked at the use of a simple saline nasal spray. Xlear is a saline nasal spray that also contains xylitol and grapefruit seed extract. Similarly, in the prior lawsuit, the FTC refused to consider simple saline nasal spray RCT studies as substantiation for Xlear. (The FTC refused: despite having no evidence that Xlear was less effective than plain saline; and, despite evidence submitted by Plaintiff showing that Xlear was more effective in many respects than a simple saline spray.) As a result, Plaintiff reasonably fears that the FTC would use any statement Plaintiff would make about the Lancet Study, that was not directly at issue in the prior litigation, even if entirely factual, as grounds for a new FTC lawsuit against Plaintiff under the FTC's practice and unlawful interpretation of sections 5(a) and 12.

33. Similarly, while many Americans are behaving like the COVID-19 pandemic is finished, the virus continues to mutate and remains a serious health risk. According to the Centers for Disease Control ("CDC"), from January 1, 2025 up to April 26, 2025, at least 10,564 Americans died from COVID-19. CDC, Provisional COVID-19 Mortality Surveillance, reviewed May 5, 2025, available at https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm. At the same time, less than one in five Americans are currently vaccinated against the disease.

34. In the course of the FTC's prior lawsuit a series of new studies, both *in vitro* and RCT, were published documenting the efficacy of nasal sprays as a means to both prevent COVID-19 infections and minimize the duration and severity for those who are already infected. These studies, for example, include the large Lancet Study discussed above. But for the fear of FTC enforcement, Plaintiff would right now be taking action to truthfully educate people about these studies and the benefits of nasal hygiene, to include using Xlear, as a COVID-19 countermeasure.

35. Any such future statements would be grounds for a FTC enforcement action under the Agency's current unlawful substantiation scheme.

36. As discussed above, Plaintiff also makes, markets and sells xylitol-based dental hygiene products under the Spry brand. There is scientific data that supports the efficacy of xylitol in dental hygiene, specifically because it impairs the ability of the bacteria that causes dental decay to multiply and produce acid. Given ongoing efforts to reduce the use of fluoride, from both a commercial and public interest perspective, Plaintiffs should be actively educating people about the use of xylitol-based dental hygiene generally, and Plaintiff's products specifically.

37. Any such statements would likely run afoul of the FTC's interpretation of the FTC Act as requiring substantiation, in particular RCT substantiation. The research demonstrating xylitol's efficacy generally is not product specific. However, there is no evidence that shows the xylitol in Plaintiff's Spry products is any less effective than the xylitol used in this research. Indeed, decades of real-world experience with Spry products shows their efficacy in promoting dental hygiene. However, under the FTC's interpretation of the FTC Act, as demonstrated in the prior lawsuit, Plaintiff cannot rely on general efficacy data to support a

product claim. Which is to say, it is highly likely that if Plaintiff made any such claim about its Spry dental products, Plaintiff could face another FTC enforcement action. As a result, Plaintiff is presently precluded from making truthful, not misleading, and not deceptive statements about Spry products.

38. The prior dismissed litigation did not deal with Plaintiff's Spry dental hygiene products. The suit also did not directly address statements regarding Plaintiff's Spry products, or statements regarding the use xylitol to promote dental hygiene and health. The FTC would most certainly aver that any such potential claims are not covered by the dismissal of the prior action. As such, should Plaintiff make any such statements, Plaintiff fears that the FTC would not be barred from bringing an enforcement action by the dismissal in the prior lawsuit.

39. But for the fear of FTC enforcement based on the agency's impermissible interpretation of the law, Plaintiff would be taking action to truthfully educate people about these studies and the benefits of xylitol-based dental hygiene generally, and Plaintiff's Spry products specifically. In addition to the harm this causes the public, it also directly harms Plaintiff in loss of sales and general awareness of Plaintiff and its products in the marketplace.

40. Having already been sued by the FTC for these exact sorts of statements, and in light of the December 2022 published guidance, Plaintiff's fears are reasonable, particularized, and justiciable. *See Elrod v. Burns*, 427 U.S. 347, 373, (1976) (plurality opinion)("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury."); *see also Braidwood Mgmt. v. Equal Emp't Opportunity Comm'n*, 70 F.4th 914 , 926-27 (5th Cir. 2023) (chilling effect on Constitutional rights from potential enforcement satisfies basis for seeking declaratory relief).

41. The chilling effect of the FTC's substantiation scheme is currently injuring Plaintiff's First Amendment rights, as well as causing them to lose business opportunities. Moreover, by denying the public information that could help them avoid illness, the FTC's actions are causing real and significant harms to the American people by censoring information that would enable better informed decisions regarding their own health. These harms are real, now ongoing and are specific to the Plaintiff's interests.

42. The issue is appropriate and fit for judicial determination. This inherently legal issue has never been resolved by any court, and certainly not by any court whose decisions bind this Court. As such it is–by definition—not hypothetical.

43. This issue is a pure question of law—a facial challenge to an interpretation. It requires no additional factual inquiry. *See New Orleans Pub. Serv., Inc. v. Council of New Orleans*, 833 F.2d 583, 586-87 (5th Cir. 1987). As such the controversy is the controversy is fit (ripe) for judicial determination.

44. Simply put, Plaintiff should not be forced into the Hobson's choice of either refraining from marketing its products as it wishes, or doing so and suffering the significant burdens of a future enforcement action—having already suffered the incredible expense and other harms of the prior case—in order to obtain a determination of this issue. *See MedImmune, Inc. v. Genentech, Inc.,* 549 U.S. 118, 128–129, 127 S.Ct. 764, 166 L.Ed.2d 604 (2007) ("[W]here threatened action by government is concerned, we do not require a plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat").

45. When this Court issues the declaratory relief sought, the controversy giving rise to these harms to the Plaintiff will be ended. Both Plaintiff and the FTC will go forward with a clear understanding of what Sections 5(s) and 12 of the FTC do and do not require.

B. The FTC's Interpretation of Sections 5(a) and 12 as Requiring Substantiation is Invalid Under the Supreme Court Decision in *Looper*

46. In the prior case, the FTC alleged, primarily, that Plaintiff violated the FTC Act by making statements about Xlear Nasal Spray without adequate substantiation, specifically RCT substantiation, for the claims. It was the FTC's position that a party making a statement bears the burden of proving that the statement is supported by one or more RCTs—independent of whether the statement is objectively true and/or not misleading. Which is to say, under the FTC's substantiation scheme, a party is guilty of violating the FTC Act if it makes a statement that is objectively true, not misleading, but lacks substantiation (RCT evidence).

47. The FTC interpretation (the FTC Act requires a party making a statement must prove substantiation and substantiation requires RCTs) is not unique to Plaintiff's case. In case after case, the FTC has charged companies with violating the FTC Act because the defendant lacked RCT substantiation. *See*, *e.g.*, *FTC v. COORGA Nutraceuticals Corp*., 201 F. Supp. 3d 1300, 1309 (D. Wyo. 2016) ("The FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with competent and reliable scientific evidence." (internal quotations omitted)). Indeed, Plaintiff is aware of no case where the FTC did not assert that claims must be supported by RCT evidence to pass muster under these sections of the FTC Act.

48. The FTC interpretation requiring RCT substantiation is also reflected in the 2022 "Health Products Compliance Guidance." Exhibit B. That Guidance provides:

> Sections 5 and 12 of the FTC Act, along with the FTC's policy statements on deception and advertising substantiation, are the foundation of FTC truth-in-advertising law, and can be distilled down to two common-sense principles: 1. Advertising must be truthful and not misleading; and 2. Before disseminating an ad, advertisers must have adequate substantiation for all objective product claims conveyed, expressly or by implication, to consumers acting reasonably. A deceptive ad is one that contains a material misrepresentation or omission that is likely to mislead consumers acting reasonably under the circumstances. The type of substantiation needed for a claim depends on many factors, including the product

> being marketed and the nature of the claim. As a general rule, however, claims about the health benefits or safety of foods, dietary supplements, drugs, and other health-related products require substantiation in the form of competent and reliable scientific evidence.
>
> . . .
>
> [In making the determination if a statement is substantiated], the FTC gives great weight to accepted norms in the relevant fields of research and consults with experts in those fields . . . . Randomized, controlled human clinical trials (RCTs) are the most reliable form of evidence and are generally the type of substantiation that experts would require for health benefit claims. Although there is no requirement for a specific number of RCTs, the replication of research in an independently-conducted study adds to the weight of the evidence.

Put simply, the 2022 Guidance makes plain that: (1) the FTC admits it goes beyond the statutory requirements that advertising "be truthful and not misleading," adding a substantiation requirement found nowhere in the text of the FTC Act; and (2) the FTC imposes as a *de facto* (never promulgated) rule that every health-related product statement must be backed by two or more RCT studies or else the statement violates the FTC Act.

49. Prior to the Supreme Court's decision in *Loper,* a series of other courts deferred to the FTC's interpretation of the FTC Act requiring a party making a product statement to prove substantiation with one or more RCTs. *See*, *e.g.*, *POM Wonderful, LLC v. F.T.C.*, 777 F.3d 478 (D.C. Cir. 2015); *Thompson Medical Co., Inc. v. F.T.C.*, 791 F.2d 189 (D.C. Cir. 1986) ("The Commission has special expertise in determining what sort of substantiation is necessary to assure that advertising is not deceptive. We decline to interfere with its exercise of that discretion in the circumstances of this case.…").

50. None of these cases are controlling in this circuit. As a result, it is an open question within the Tenth Circuit whether the FTC can require a regulated party to present substantiation to justify any claims made, when that party has not previously been adjudicated as

having violated the FTC Act, and/or entered into a consent/administrative settlement/order/agreement with the FTC that calls for substantiation of claims.

51. Moreover, all of these cases were decided under the vastly more deferential standard for judicial review of agency actions under *Chevron*, which was in place prior to *Loper*. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

52. Beyond that, Plaintiff can find no decision by any federal court that undertook the statutory analysis required to determine if the FTC's interpretation—that claims are actionable under the FTC Act if they are merely unsubstantiated, and that the advertiser bears the burden of proving substantiation in enforcement actions—is valid, even under the deferential *Chevron* standard—let alone *Loper*'s more rigorous review.

53. In *Loper*, the Supreme Court explicitly rejected *Chevron* deference to agency interpretations. Under *Loper*, a court must reject an agency's statutory interpretation unless the court, "after applying all relevant interpretive tools, concludes" the interpretation is the best reading of the statute. *Loper* at 859. "In the business of statutory interpretation, if it is not the best, it is not permissible." *Id.*

54. The *Loper* analysis works hand in glove with the Supreme Court's decision in *West Virginia v. EPA*, 597 U.S. 697, 735 (2022). In *West Virginia v. EPA* the Court held that "[a]gencies have only those powers given to them by Congress, and 'enabling legislation' is generally not an open book to which the agency may add pages and change the plot line." *Id.* at 722 (cleaned up). Which is to say, agencies are constrained to implementing statutes as they are enacted, not as they are re-imagined by the agency. *Id*. at 2261 ("[I]t thus remains the responsibility of the court to decide whether the law means what the agency says.")

55. As a result, under *Loper*, a court reviewing an agency action must first examine the statute to determine if the statute is clear on its face. *King v. Burwell*, 576 U.S. 473, 486 (2015) "If the statutory language is plain, we must enforce it according to its terms." *Id*.

56. If the reviewing court determines the words are ambiguous, the court must then go back to the words and, using all the court's tools of statutory interpretation, determine what is the "best" meaning of the statutory language. If the agency action in question does not comport with what the court determines is the best reading of the statute, then the court must reject the agency's interpretation. *Loper* at 859 ("In the business of statutory interpretation, if it is not the best, it is not permissible.")

57. The FTC's interpretation that the FTC Act requires substantiation fails all these tests outright.

58. First, the relevant language in the FTC Act is not ambiguous. *See Allen v. Geneva Steel Co.* (*In re Geneva Steel Co.*), 281 F.3d 1173, 1178 (10th Cir. 2002)(A statute is ambiguous if it, "is capable of being understood by reasonably well-informed persons in two or more different senses.") Here, "false" (the contrapositive of "truth) is a well understood concept that needs no interpretation. The same is true of the term "unfair."

59. The specific language in Sections 5(a) and 12 of the FTC simply does not require substantiation because the word "substantiation" never appears in these provisions. Nor do these provisions include any words that might suggest a substantiation requirement—such as "proof", "test", "testing", "RCT", "basis", "evidence," "study," "data," and the like. Rather, the plain language of the FTC Act, prohibits "unfair or deceptive acts" (section 5(a), 15 U.S.C. § 45(a)), "false advertisements" (section 12, 15 U.S.C. § 52), "deceptive acts or practices" (section 12, 15 U.S.C. § 52). The statute never mentions the word "substantiation" let alone a requirement that

substantiation is a prerequisite to lawful claims. 15 U.S.C. §§ 45(a), 52. On this precise point the Seventh Circuit Court of Appeals in *FTC v. QT, Inc.*, 512 F.3d 858 (7th Cir. 2008), held:

> Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand.

Id. (discussing FTC's substantiation interpretation).

60. Drawing on the Supreme Court's analogy, the FTC has impermissibly added pages—really an entire chapter—to the book. *West Virginia v. EPA.* at 722 (cleaned up) (enabling legislation is not an "open book to which the agency may add pages and change the plot line.") This should be the end of story. *United States v. Koerber*, 10 F.4th 1083, 1112 (10th Cir. 2020) ("Absent ambiguity, our analysis ends there.")

61. Second, even if this Court finds these sections are ambiguous, applying the tools of statutory interpretation it is obvious that the FTC's interpretation is far from the "best" interpretation.

62. Perhaps the best evidence that the FTC's substantiation scheme is not the best reading of Sections 5(a) and 12 is that for over 60 years the FTC itself did not interpret the statute this way. Plaintiffs' counsel cannot find a single case or administrative proceeding before 1972 in which the Commission—or anyone else, for that matter—took the position that advertising claims were even arguably deceptive, let alone *deceptive as a matter of law*, simply because the claims were unsubstantiated. It is nonsensical to suggest that the "best reading" of the statute is one that neither the Congress nor the Commission gave it for the first sixty years of its existence.

63. The second, and most obvious, proof that the FTC's interpretation requiring substantiation is not the "best" is that the specific term, "substantiation", does not appear in the

statutory language. Neither do any of its derivatives or synonyms. Nor does the statute contain anything remotely suggesting the underlying concept. If Congress had intended the FTC Act to include substantiation it could and would have written that requirement into the law. It did not.

64. Moreover, the concept of whether a claim is substantiated is fundamentally different from whether it is false or deceptive. Not all claims that lack substantiation are false or deceptive. Indeed, it is widely acknowledged, from both a scientific and common-sense standpoint, that claims can be (a) true but unsubstantiated, and (b) false but substantiated.

65. All told, the FTC lacks any statutory basis for its interpretation of the FTC Act as equating a lack of substantiation with a claim being false or misleading.

66. Additionally, the Commission's interpretation of the FTC Act should further be rejected as not "best" because it violates the maxim "to avoid an interpretation of a federal statute that engenders constitutional issues if a reasonable alternative interpretation poses no constitutional question." *Gomez v. United States*, 490 U.S. 858, 864 (1989). The FTC's substantiation requirement violates the First Amendment because, for example, it has the potential to punish protected speech that is neither false nor deceptive.

67. A reading of the FTC Act that prohibits every unsubstantiated claim on every product, regardless of whether the claim is true, and irrespective of the type of product at issue or the circumstances presented, is overbroad and cannot survive Constitutional scrutiny. (Again, a claim can be true but not substantiated.)

68. As discussed in detail below, the FTC's interpretation also violates the Equal Protection Clause by improperly shifting the FTC's burden of proof onto defendants.

69. Further the history of Sections 5(a) and 12 show that the Congress could not have intended to create a substantiation requirement. Sections 5 and 12 of the FTC Act were enacted

in 1914 and 1938, respectively. Even in 1938, clinical substantiation was not in a widespread scientific parlance, let alone practice. The very first double-blind study (Patulin for colds) did not occur until 1943; the first randomized controlled of trial of streptomycin did not occur until 1946. *See* Bhatt A., "Evolution of clinical research: a history before and beyond James Lind," Perspect Clin Res. 2010 Jan;1(1):6-10. PMID: 21829774; PMCID: PMC3149409. According to the FDA, modern clinical trials (substantiation in FTC terms) did not become a part of evidence-based medicine in the United States until after World War II. *See* FDA, FDA and Clinical Trials: A Short History, undated, at 2, available at https://www.fda.gov/media/110437/download. It is implausible to suggest Congress intended the FTC Act to require a then-nonexistent scientific principal.

70. In sum, the FTC's substantiation scheme reads into the FTC Act words and concepts that simply do not exist in the law; defies the FTC's own, historical interpretation of the statute; violates both the First Amendment and Equal Protection clauses of the Constitution; flies in the face of the legislative history of the FTC Act; and imposes requirements that history shows the Congress could not possibly have sought to enact.

71. As such it is not the "best" reading of the statute as required under *Loper*. In fact, it isn't a reading of the law, it is a fiction of FTC's own invention. Were it a standalone book it should be called "The World According to the FTC."

C. The FTC's Interpretation of Sections 5(a) and 12, in Effect, Impermissibly Shifts the Burden of Proof, in Violation of the Equal Protection Clause

72. It is axiomatic that the plaintiff in any lawsuit generally bears the burden of proving its claims. *See, e.g., National Council Against Health Fraud, Inc. v. King Bio Pharmaceuticals, Inc.*, 107 Cal. App. 4th 1336, 1344 (Cal. App. 2003) ("a plaintiff in a false

advertising or unlawful competition action has the burden of producing evidence that the challenged advertising claim is false or misleading.").

73. The FTC's substantiation scheme impermissibly shifts that burden of proof from the Government onto defendants. In substantiation enforcement actions, the FTC begins by filing a complaint (either in Federal court or administratively). That complaint alleges that the defendant made certain claims without adequate substantiation, which the FTC alleges violated the FTC Act. For the case to proceed, these allegations must be able to survive a Fed. R. Civ. P. 12(b)(6) motion to dismiss. In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) the Supreme Court set the standard of proof for the Plaintiff's pleading as merely "plausible." *Id.* at 555.[1]

74. In contrast to the 12(b) (6) pleading standard, except where otherwise provided by statute, in civil cases, before any plaintiff—including the government—can flip the burden of proof onto a defendant (requiring the defendant to now prove innocence or a defense), the plaintiff must first prove that the defendant committed the infraction by prima facie evidence. *See Dir. v. Greenwich Collieries*, 512 U.S. 267, 281 (1994).

75. However, in FTC substantiation cases, the FTC pleads that a party has violated the FTC Act by failing to have substantiation. At this stage, the FTC has not proven any element of its case to any level of proof.

76. Yet, in such cases, the FTC's mere pleading lack of substantiation flips the burden and compels the defendant to prove substantiation. Simply put, in cases to date (prior to this

[1] In the follow-on case, *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the Supreme Court extended the requirement of plausibility to all civil cases. *Id*. at 678. *Iqbal* also went further and held that a plaintiff's mere allegations are not entitled to the assumption of truth when they are mere accusations unsupported by facts. *Iqbal*, 556 U.S. at 679. However, merely pleading facts is not actual proof of those facts. Rather plead facts serve to enable the allegations to stand as plausible, which is what is required to survive a Fed. R. Civ. P. 12(b)(6) motion to dismiss.

Loper challenge), if the FTC alleges that the defendant lacks the FTC-requisite level of substantiation, guilt is assumed, *even though the Government has proven nothing*. *See, e.g*., *Fed. Trade Comm'n v. Johnson*, 96 F. Supp. 3d 1110 (D. Nev. 2015) (*citing FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 8 (1st Cir. 2010) (if an advertiser lacks substantiation for their claims, a violation of the FTC Act is assumed because the claims are considered deceptive as a matter of law).

77. But any assumption that a claim is false or misleading simply because it is not substantiated to the degree the FTC believes is required is inherently flawed. The mere fact that a statement lacks a specific kind of substantiation does not mean the statement is "false", "deceptive" or "unfair." For example, in science there is a truism, "there is no RCT evidence that a parachute works." *See* Richard Harris, *Researchers Show Parachutes Don't Work, But There's A Catch*, NPR, Dec. 22, 2018, available at https://www.npr.org/sections/health-shots/2018/12/22/679083038/researchers-show-parachutes-dont-work-but-there-s-a-catch. Or as Judge Easterbrook explained in *FTC v. QT*, "[T]he seller of an adhesive bandage treated with a disinfectant . . . . does not need to conduct tests before asserting that this product reduces the risk of infection from cuts . . . . It may be debatable how much the risk of infection falls, but the direction of the effect would be known, and the claim could not be condemned as false." *Federal Trade Commission v. QT, Inc.*, 512 F.3d 858 (7th Cir. 2008). Thus, there is neither a legal nor a logical basis for the FTC to equate a lack of substantiation with the only things that the FTC Act actually prohibits—that is, claims that are false or deceptive.

78. Simply put, in FTC substantiation cases pre-*Loper*, defendants are required to prove their innocence (the affirmative defense) before the FTC has to prove anything.

79. Nothing in the FTC Act authorizes the shifting of the burden of proof in FTC substantiation cases. In *Dir. v. Greenwich Collieries*, the Supreme Court held that without specific statutory authorization an agency cannot shift the burden of proof in enforcement cases to Defendants. *Dir. v. Greenwich Collieries*, 512 U.S. 267, 281 (1994).

80. In order to comport with the requirements of Equal Protection, the burdens in FTC enforcement cases must be reset to make clear that the Agency bears the burden of proving the elements of the statutory violation by a preponderance of the evidence; and, the FTC Act simply does not allow the FTC to meet its burden by merely alleging or even showing a lack of substantiation.

VI. RELIEF SOUGHT

1. Plaintiff respectfully asks this Court to issue declaratory relief declaring that the FTC's requirement of substantiation is not authorized under the FTC Act and is impermissible under the Supreme Court's holding in *Loper*. In so doing, Plaintiff asks the Court to strike down the FTC's substantiation requirements under sections 5(a) and 12 of the FTC Act.

2. Plaintiff also respectfully requests that this declaratory relief provide that any FTC action taken under the guise of sections 5(a) and 12 is limited to enforcing the actual the language of the FTC Act, which prohibits "unfair or deceptive acts" (section 5(a): 15 U.S.C. § 45(a)), "false advertisements" (section 12: 15 U.S.C. § 52), and "deceptive acts or practices" (section 12: 15 U.S.C. § 52). To this end, Plaintiff requests that this Order make clear that the FTC may not impose the entirely unauthorized substantiation requirement on parties making statements under sections 5(a) and 12 of the FTC Act.

3. Plaintiff also respectfully requests that this declaratory relief clearly require that, in any enforcement matter, the FTC bears the burden of proving the elements of the statutory

violation by a preponderance of the evidence—and such evidence cannot consist solely of a defendant's lack of evidence of an affirmative defense (i.e., substantiation). Simply, the FTC must prove that the defendant has committed "false", "unfair or deceptive acts". Then, and only then, must a marketer offer evidence to rebut the FTC's allegations.

4. Plaintiff also respectfully requests this Court to provide any other relief that the Court may determine is lawful and appropriate.

Respectfully submitted this 18th day of June 2025

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